

ATTORNEY'S DOCKET NO.: 2001796-0008

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Bramley, *et al.* Examiner: Woitach, Joseph T.  
Serial No.: 10/087,667 Group Art Unit: 1632  
Filed: February 28, 2002  
For: TREATMENT OF STAPHYLOCOCCUS INFECTIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**TRANSMITTAL**


Enclosed please find the following documents regarding the above-referenced matter:

1. Written Assertion of Small Entity Status Under 37 CFR §1.27(a)(3) Non-Profit Organization (1 page); and
2. Return Postcard.

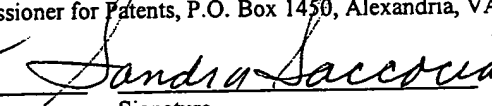
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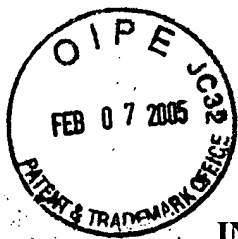
Respectfully submitted,

Dated: February 4, 2005

  
Monica R. Gerber, M.D., Ph.D.  
Reg. No. 46,724

PATENT DEPARTMENT  
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Sandra Saccoccia	
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**Box Issue Fee**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**TRANSMITTAL OF ISSUE AND PUBLICATION FEE**

In response to the Notice of Allowance mailed November 4, 2004, in the subject patent application, enclosed is the Comments on Statement of Reasons for Allowance; Issue and Publication Fee Transmittal together with a check for \$1,030.00 to cover the Issue Fee and 10 soft copies. Also enclosed is a copy of the Transmittal for Written Assertion of Small Entity Status Under 37 CFR § 1.27(a)(3); a copy of Written Assertion of Small Entity Status Under 37 CFR § 27(a)(3); a copy of the Return Postcard for same; and Return Postcard (Issue Fee).

Please charge any deficiencies or overpayments to our Deposit Account No. 03-1721.

Respectfully Submitted,

Monica R. Gerber, M.D., Ph.D.

Agent for Applicant

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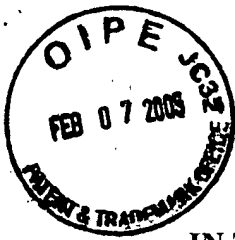
2-4-05 Sandra Saccocia

Date

Signature

Sandra Saccocia

Typed or Printed Name of person signing certificate



Attorney Docket No: 2001796-0008

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Applicant: Bramley, et al. Examiner: Woitach, J.  
Serial No.: 10/087,667 Art Unit: 1632  
Filing Date: February 28, 2002  
Title: TREATMENT OF STAPHYLOCOCCUS INFECTIONS

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on 12-9-02  
Pamela Saccoccia

Sir:


**COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE**

This submission is made in response to the examiner's statement of reasons for allowance as set forth in the Notice of Allowability. In the examiner's statement of reasons for allowance the examiner acknowledged specific limitations in the claims that were important in addressing the rejection under 35 U.S.C. 112, first paragraph. The examiner also stated that the expression of functional proteins in the mammary gland of non-human mammals and the antibacterial properties of lysostaphin were known at the time of filing but that "the present disclosure is the first to demonstrate that alterations to the protein resulting in modification to the glycosylation of lysostaphin would not adversely affects (*sic*) its properties and result in a functional protein when expressed by a cell." The examiner further stated that the two "essential elements" of the claim were known in the art but that the art did not provide the motivation to combine them into the instantly claimed invention. The examiner then stated that the disclosure was the first to show "that altering the glycosylation pattern does not adversely affect the function of lysostaphin", which would not necessarily have been expected.

Applicants submit that the record of prosecution makes clear the reasons for allowance of the claims. The prosecution record points out the examiner's reasons for rejection, and Applicants' replies address those rejections. Applicants would like to clarify that lysostaphin encoded by the naturally occurring lysostaphin gene is not normally glycosylated in bacterial

cells. The present disclosure was the first to show that lysostaphin encoded by a naturally occurring lysostaphin coding sequence, modified by addition of a mammalian signal sequence that was added in order to direct the protein to the mammalian secretory pathway such that it is secreted, is glycosylated when expressed in mammalian cells and is secreted in an inactive form. The present disclosure was also the first to demonstrate that secretion of lysostaphin by mammalian cells in active form could be achieved by altering the sequence of lysostaphin so as to disrupt glycosylation that would otherwise occur in mammalian cells. These results were both novel and nonobvious and distinguish the claimed invention from the prior art.

Respectfully submitted,

A handwritten signature in cursive script, reading "Monica R. Gerber". The signature is written in black ink and is positioned above a horizontal line.

Monica R. Gerber

Registration Number 46,724

Date: February 4, 2005

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